REMARKS

This is in response to the Office Action dated Jun 07, 2007 for US Application Serial No. 10/023,427. Applicants have carefully reviewed and considered the office action mailed on Jun 07, 2007, and documents cited therewith.

Claims 72-90, 93, 96-97, and 99 are currently pending. Claims 1-71, 98 and 102 are cancelled. Claims 100-101 are withdrawn. Claims 72, 73, 75, 76, 78, 80, 83, 85, 86, 88, 89, 93, 96, and 97 are amended.

According to the official action, claims 100-102 were withdrawn from consideration as being directed to a non-elected invention under 37 CFR 1.142 (b).

The Examiner's attention is drawn to the Official Action dated August 19, 2003, where Examiner grouped the as filed claims 1-17, 52, 54, 55 and 63 drawn to a composition comprising a polymer, a delivery system formed from said composition and a method of treatment comprising administering said composition as Group I.

The Examiner's attention is also drawn to Official Action dated December 2, 2003, where the Examiner withdrew the as filed claims 3, 9, 18-51, 53, 56-62, 64-68 from consideration and examined claims 1, 2, 4-8, 10-17, 52, 54, 55 and 63.

Claim 52 was directed towards a method of preventing or treating a health disorder, disease or medical condition comprising administering a composition according to claim 1 to a patient in need thereof. Furthermore, in the official action dated Dec 2, 2003, the Examiner rejected claim 52 under 35 U.S.C 112, first paragraph stating that the specification while being enabling for a method for suppressing serum testosterone, does not reasonably provide enablement for treating/preventing any health disorder, disease or condition.

Further, in the Official Action dated November 30, 2004, the Examiner withdrew the rejection of claim 52 under 35 USC 112, first paragraph, based on amendment of claim 52 by the applicant, wherein the applicant deleted the word "preventing" and added "wherein the health disorder, disease or medical condition can be treated by the biologically active agent of claim 7".

In a response filed by applicant dated May 25, 2005, applicant filed new claims 72-97 and cancelled 1-71 claims. Here claims 91 and 92 correspond to as filed claim 52. In an official action dated August 10, 2005, examiner objected to claims 91 and 92 under 37 CFR 1.75 (c) as being in an improper form based on multiple dependencies.

So, accordingly, applicant in its recent amendment dated March 8, 2007, cancelled claims 91 and 92 and instead added new claims 100, 101 and 102 to overcome the objection under 37 CFR 1.75 (c).

Claim 100 corresponds to same as filed claim 52 and amended claims 91 and 92, but instead specifically claims method of treatment of a specific disorder i.e. prostate cancer, support for which can be found in example 16 of the specification.

Claim 101 corresponds to same as filed claim 52 and amended claims 91 and 92, but instead specifically claims a method of treatment of a specific disorder i.e. breast cancer, support for which can be found on pages 39-40 and figure 3 of the specification.

Claim 102 is cancelled, so consideration for claim 102 is rendered moot.

Based on the above, it is clear that the newly added claims 100 and 101 (corresponding original claims 52, and claims 91 and 92) were already grouped by the examiner under Group I as the elected invention. The corresponding claims were considered by the examiner throughout the prosecution of this application, are a part of the elected invention and not directed towards a non-elected invention.

Therefore, it is respectfully requested that claims 100 and 101 be rejoined and examined in this application.

The Examiner objected to specification as failing to provide proper antecedent basis for the claimed subject matter of claim 86 under 37 CFR 1.75 (d) (1).

Claim 86 has been amended. This claim defines that concentration of surfactant or emulsifier is 0.01-50%w/w with respect to the continuous hydrophobic-gelled non-polymeric matrix oil phase. This is supported by the published specification at paragraph [0063] "more preferably the concentrations are in the range 0.01-50%w/w with respect to the continuous oil phase". This corresponds to paragraph [00061] of the application as originally filed.

Therefore, in light of the amended claim and these citations, the specification provides proper support for the limitation in claim 86. Applicants respectfully request that this objection under 37 CFR 1.75 (d) (1) be withdrawn.

The 35 U.S.C. 112 Rejection/New Matter

The Examiner rejected claims 72-90, 93 and 96-99 under 35 U.S.C 112, first paragraph, as failing to comply with the written description requirement.

Claim 72 has been amended. This claim now does not contain the term "wherein no aqueous phase is present in said drug delivery system" and "comprising" has been replaced with "consisting of" in accordance with the Examiner's suggestion in the Office Action dated May 3, 2006 which itself excludes an aqueous phase. All other claims are dependent directly or indirectly from Claim 72. Thus, this amendment of claim 72, applies to the other dependent claims.

Therefore, in light of amended claim, there is no new matter and hence applicants respectfully request that this new matter rejection be withdrawn.

Claims 72-90, 93, and 96-99 are rejected under 35 U.S.C 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter.

The examiner objected to term "non-preformed microparticles as being unclear. Accordingly, claim 72 has been amended to replace the term "non-preformed microparticles" with "gelled droplet in oil dispersion".

The examiner pointed towards the ambiguity in claim 83, which recites lactic acid as a biologically active agent with regard to specification at paragraph [0078], which mentions lactic acid as biologically inactive agent. Claim 83 has been amended to delete the term "lactic acid".

The examiner mentions that claim 93 requires the composition of claim 72 to further contain biological agent and it is not clear how the composition or delivery system that already contains biologically active agent further contains biologically active agent. Accordingly, the claim 93 has been amended to delete the term "biologically active agent".

The examiner mentions that claim 78 contradicts the concept of claimed delivery system of claim 72.

Claim 78 in no way requires that discontinuous phase in claim 72 contains water. Claim 78 recites only the oils, which can be used in continuous oil phase of delivery system of claim 72. Claim 72 has been amended and no longer contains the term "free of water or aqueous phase".

The examiner mentions that claim 97 as presented contradicts the concept of the claimed delivery system of claim 72.

The "aqueous medium" as mentioned in claim 97 refers to aqueous medium present within, in or on the body i.e body fluids and is not referring to an aqueous medium or water in the delivery system as such. It is clear that the delivery system of the present invention is an *in situ* delivery system, wherein the microparticles are formed *in situ*, when the discontinuous phase comes in contact with an aqueous medium i.e. aqueous fluid present within, in or on a body. The feature of microparticles being formed *in situ* is defined in Claims 73-84.

The examiner mentions that there is insufficient antecedent basis for the limitation "the concentration" in claims 85 and 86 as claims 72, 76 and 80 do not recite this phrase.

Claims 85 and 86 are amended to delete the term "the concentration".

The examiner mentions that there is insufficient antecedent basis for the limitation "the size of the microparticles" in claims 88 and 89.

Claims 88 and 89 have been amended to delete "the size" and add – a size. --

The examiner mentions that there is insufficient antecedent basis for the limitation "the primary mechanism of release" and "the therapeutic agent" in claim 96 as claim 72 does not recite primary mechanism or therapeutic agent.

Accordingly, claim 96 is amended to delete the term "primary mechanism of release" and "therapeutic agent". The term "the primary mechanism of release" has been replaced with "mainly". The term "therapeutic agent" is replaced with "biologically active agent".

The examiner mentions that there is insufficient antecedent basis for the limitation "the secondary mechanism of release" and "the therapeutic agent" in claim 97 as claim 72 does not recite secondary mechanism or therapeutic agent.

Accordingly, claim 97 is amended to delete the term "secondary mechanism of release" and "therapeutic agent". The term "the secondary mechanism of release" has been replaced with "additionally". The term "therapeutic agent" is replaced with "biologically active agent".

In view of all above amendments and citations, claims 72-90, 93 and 96-99 comply with the written description requirement. Applicants respectfully request that this rejection under 35 U.S.C 112, first paragraph be withdrawn.

The 35 U.S.C 102 Rejection

According to the Official Action, Claims 72-79, 84, 87, 93 and 96-99 are rejected anticipated by Jain, "Controlled Drug Delivery from a Novel Injectable *In Situ* Formed Biodegradable PLGA Microsphere System", Dissertation, University of Rhode Island, 1998 under 35 USC 102(b). A copy of the dissertation is being submitted with the Information Disclosure Statement being filed herewith.

The examiner also rejected claims 72-79, 84, 87, 93 and 96-99 under 35 U.S.C 102 (a) as being anticipated by Jain et al. ["Comparison of various injectable protein loaded biodegradable poly (lactide-co-glycolide) PLGA devices: In situ formed implant versus in situ formed microspheres versus isolated microspheres", in Pharmaceutical Development and Technology, 5(2), 201-207 (2000)].

The examiner rejected claims 72-80, 82, 84, 87, 93 and 96-98 under 35 U.S.C 102(a) as being unpatentable over Jain ["The manufacturing techniques of various drug loaded biodegradable poly (lactide-co-glycolide) PLGA devices" in Biomaterials, 21, (2000), 2475-2490].

The examiner's attention is drawn towards the fact that details of the work incorporated in dissertation of Jain, the abstract of which is quoted by the examiner is published as:

1) Jain et. al. "Controlled drug delivery from a novel injectable in situ formed biodegradable PLGA microsphere system," in Journal of Microencapsulation, 17 (3), 343-362 (2000).

Other prior art references quoted by examiner, which describes the composition of Jain, are:

1) Jain et al, "Comparison of various injectable protein loaded biodegradable poly (lactide-co-glycolide) PLGA devices: In situ formed implant versus in situ formed microspheres versus isolated microspheres", in Pharmaceutical Development and Technology, 5(2), 201-207 (2000).

2) Jain "The manufacturing techniques of various drug loaded biodegradable poly (lactide-co-glycolide) PLGA devices" in Biomaterials, 21, (2000), 2475-2490.

The examiner's attention is drawn towards the fact that the above two prior art references of Jain (Pharmaceutical development and Technology & Biomaterials) cannot be treated separately and have to be considered along with Jain (Journal of Microencapsulation), as and when required, as Jain (Journal of Microencapsulation) reference describes specifically the same study in detail with different operational variables. Additionally, the article from Biomaterials stems from the article in the Journal of Microencapsulation reference. The article Biomaterials was published later in December 2000 and reports a small part of the detailed study mentioned in Journal of Microencapsulation reference, which was published in May 2000.

The two compositions, the one described by Jain in the above cited dissertation and the instant application are different.

A comparative description highlighting the differences between the respective compositions is provided below:

S.No	**Jain et. al**	**Bhagwatwar et. al. (US 2003/0049320A1) (Instant application)**
1	The continuous phase is simple oil phase	The continuous phase is gelled oil phase, obtained from the gelling of oil by the gelling action of sorbitan monostearate, sorbitan monopalmitate or a mixture

		thereof. (See Claim 80)
2	The solvents used for forming polymer solution or discontinuous phase are water immiscible solvents.	The solvents used for forming polymer solution or discontinuous phase are water miscible solvents. The present inventors have found for the first time that certain nonionic emulsifiers such as sorbitan monostearate and sorbitan monopalmitate are capable of gelling water miscible or soluble non-volatile organic solvents.
3	Only PEG is being used as a sole solvent for drug only and triacetin for polymer only. PEG is not either disclosed or used as a polymer being capable of forming microspheres.	PEG is mainly used as a solvent for polymer and additionally for drug also and besides that a lot of suitable solvents have been disclosed for drugs and polymers. In fact, here PEG is also been used as a water-soluble polymer for forming microspheres.
4	It has been mentioned that presence of tween 80 is necessary for formation of microspheres and it is being used here as surfactant in discontinuous phase. This reference teaches or motivates the use of tweens in discontinuous phase.	Tween 80 is not being used in any of the examples described in this application in discontinuous phase. Whereas, applicants applicants demonstrated formation of microspheres even in absence of tweens.
5	The formation of delivery system is demonstrated for only PLGA as polymers, Triacetin as solvent and spans/tweens as emulsifiers. The applicability for other classes of polymers, with different physicochemical characteristics and biodegradability profiles, is not demonstrated.	Applicants have demonstrated the formation of delivery system with wide range of polymers, surfactants/emulsifiers and solvents. It is not obvious to use the other set of polymer, as the formation of such type of delivery system is highly dependent on type and concentration of polymer.

The droplet-in-oil dispersion described by Jain et. al. are different from those described in the instant application as described in table above.

A printed publication will anticipate a claim under 35 U.S.C. 102 (b) " only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) MPEP § 2131. In other words, a printed publication must include all "limitations" of a claim (Richardson v. Suzuki Motor Co., 868 F. 2d 1226, 1236 (Fed. Cir. 1989)). *Merely identifying within the prior art all of the various parts of the claimed subject matter is not anticipation.* Instead "there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of invention" (Scripps Clinic & Research Found V. Genentech Inc., 927 F. 2d 1565, 1576 (Fed. Cir. 1991)).

Inherent anticipation, "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient". In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). To be inherent, an undisclosed feature must necessarily and inevitable flow from practice of what is disclosed. Id. MPEP § 2112.

The question of whether a printed publication includes all of the claim limitations, expressly or inherently, is a question of fact. Minn. Mining & Mfg. Co v. Chemque, Inc. 303 F. 3d 1294, 1301 (Fed. Cir. 2002); Schreiber, 128 F. 3d at 1477.

The present inventors have found for the first time that certain emulsifiers such as nonionic emulsifiers such as sorbitan monostearate are **capable of gelling water miscible or soluble non-volatile organic solvents**. The delivery system of the instant application is gelled droplet in oil dispersion, whereas that of Jain is simple droplet in oil type. Jain has described that it is necessary to use surfactant/emulsifier both in the oil phase and discontinuous phase. It is clear from claim 72, use of emulsifier is being described in relation to the continuous oil phase and not in the discontinuous phase. Further, Jain describes use of tween 80 only in discontinuous phase. It is also mentioned in Jain that "absence of tween 80 yielded PLGA microglobules which poorly dispersed

on coming in contact with water and hardened into an agglomerated PLGA mass (a non-microsphere product)" [See the details of PhD dissertation or published part of PhD dissertation as Jain et. al. "Controlled drug delivery from a novel injectable in situ formed biodegradable PLGA microsphere system," in Journal of Microencapsulation, 17 (3), 343-362 (2000)]. Despite the fact that tweens not are being used in discontinuous phase in instant application, applicants of the instant application are still getting a microparticle product of specific shape. It is clear from Jain et al. that if tween 80 is not used in discontinuous phase, then it is not within purview of ordinary skill in the art to get microparticles in situ as Jain strongly suggests use of tweens in discontinuous phase. If microparticles are not obtained in situ, then question of shape does not arise. Based on above citations, it is clear that shape of microparticles recited in claim 87 is not inherent to the microparticles formed from the composition of Jain. .

With regard to claim 82: Jain et al. has described that biodegradable polymers like PLGA, PLA can be used to incorporate variety of drug classes like vaccines, peptides, proteins. Jain et al. does not describe the actual use of vaccines for formulating in situ delivery system. The use of these polymers for incorporating variety of drugs is well known in the prior art. But where actually lies the difference is between the delivery systems. Delivery system of the instant application and Jain is different. Though instant application also does not describe the actual use of vaccines but it provides enough description and examples about the lacunae in the prior art delivery compositions and also the use of the instant application in overcoming these lacunae. Hence, vaccine of Jain does not meet claim 82.

Hence, Jain's delivery system does not meet requirements of claims 72, 82 and 87 and the claims dependent thereon.

In regard to claim 76, here PEG is described as a solvent for a polymer whereas Jain describes use of PEG solely as a solvent for drug. The only solvent (Triacetin) used in Jain is water immiscible solvent, whereas the solvents included in the text of claim 76

are water miscible solvents and triacetin is neither claimed nor mentioned in the specification of the instant application.

With regard to claims 77-79: In claim 77, it has been clearly mentioned that composition of instant application is **gelled** (emphasis added), whereas delivery system or composition of Jain is **not gelled**. In Jain et al. water immiscible solvent i.e. triacetin is being used, where as in the composition of the instant application, water miscible solvents are used, which gel is presence of compounds such as sorbitan monostearate or monopalmitate.

With regard to claim 84: In claim 73, "gelled droplet in oil dispersion" has been mentioned and claim 84 is dependent from claim 73. As mentioned in table above also, delivery system or composition of Jain is not a gelled droplet in oil dispersion. Since composition of instant application and that of Jain are different, hence claim 84 does not meet the in situ microparticle composition of Jain.

With regard to claim 99: In Jain et al, drug is added and present only in discontinuous phase. The examiner's attention is drawn towards the fact that the composition of Jain is droplet in oil dispersion, and when two phases are mixed, then drug remains dispersed in globules of polymer in continuous phase and is as such not present in continuous phase. When droplet in oil dispersions is made, then on mixing two phases (discontinuous phase containing drug and continuous oil phase), drug remains within droplet (entrapped in polymer) and is not mixed with continuous phase. Nowhere in Jain et al. also, it has been mentioned that drug is added in continuous phase or drug gets mixed into outer continuous phase when both phases are mixed. Additionally, cytochrome c, which is used as a drug in Jain, is a water-soluble drug, and generally continuous phase used in such case is an oil phase to prevent partitioning of drug from discontinuous phase into continuous phase on mixing of two phases as it leads to low entrapment efficiency. In claim 99, "further comprising biologically active agent in continuous phase" means that drug can be further added as such directly in continuous

phase in order to provide an initial release of biologically active agent [para 0080 of the instant application also supports this] and it does not mean that drug from discontinuous phase has leached or mixed into continuous phase. From the above citations, it is clear that Jain et al. does not meet claim 99 of the instant application.

With regard to claim 80: However, to reiterate what was discussed above, the drug delivery composition of the present invention is gelled matrix, whereas the composition of Jain et al. is not gelled matrix. The Spans have a key role in the present invention as they gel the continuous oil phase of the invention and water miscible organic solvents. The inventors of the instant application have surprisingly found for the first time that certain nonionic emulsifiers such as sorbitan monostearate and monopalmitate are capable of gelling water miscible or soluble non-volatile organic solvents. Sorbitan monostearate and monopalmitate are the only emulsifiers known to gel oils. In Jain et al, Span 80 (Sorbitan monooleate) is being used to prevent PLGA microglobules from adhering to each other and **not for gelling** (emphasis added), as their composition is not gelled matrix. Hence, claim 80 does not anticipate Jain et al.

From the above citations, it is clear that three Jain references do not anticipate the claims.

Therefore, claims 72-80, 82, 84, 87, 93 and 96-99 are not anticipated by Jain et al. and it is respectfully requested that rejection under 35 U.S.C 102 (a) be withdrawn.

The 35 U.S.C. 103 Rejection

The examiner rejected claims 81 and 85 under 35 U.S.C. 103(a) as being upatentable over Jain ["The manufacturing techniques of various drug loaded biodegradable poly (lactide-co-glycolide) PLGA devices" in Biomaterials, 21, (2000), 2475-2490].

KSR v Teleflex backs the factual enquiries set forth in Graham v John Deere Co., 383 U.S. 1,148 USPQ 459 (1966).

This is respectfully traversed.

When prior art "teaches away" from the claimed invention rather than motivating a person of ordinary skill in the art to do what patentee has done, the claimed invention is non-obvious (In re Hedges, 783 F 2d 1038, 1041 (Fed. Cir. 1986); W.L. Gore & Assocs. V. Garlock, Inc., F. 2d 1540, 1552-53 (Fed. Cir. 1983)); MPEP § § 2141.02, 2145.

With regard to Claim 81, the drug delivery composition of the present invention is gelled dispersion, whereas the composition of Jain et al. is not gelled dispersion. The Spans have a role in the invention of the instant application as they gel the continuous oil phase of the invention and water miscible organic solvents. The inventors of the instant application have surprisingly found for the first time that certain nonionic emulsifiers such as sorbitan monostearate and monopalmitate are capable of gelling water miscible or soluble non-volatile organic solvents. Additionally, sorbitan monostearate and monopalmitate are the only emulsifiers known to gel oils. In Jain et al, Span 80 (Sorbitan monooleate) is being used only as emulsifier to prevent PLGA microglobules from adhering to each other and not for gelling. It is not obvious to try these emulsifiers for making gelled composition of the present invention as there is no teaching, suggestion or motivation in Jain et al which can lead a person ordinary skill in the art to use sorbitan monostearate or sorbitan monopalmitate to gel water miscible solvents and to gel oil phase as Jain's composition is not a gelled composition. Also, when all the elements of claimed invention are not present in prior art. Therefore, claim 81 is not obvious in view of Jain.

With regard to claim 85: The examiner's attention is drawn towards the Jain et. al. ["Controlled drug delivery from a novel injectable in situ formed biodegradable PLGA microsphere system," in Journal of Microencapsulation, 17 (3), 343-362 (2000)].

At page 351 of Jain et al ["Controlled drug delivery from a novel injectable in situ formed biodegradable PLGA microsphere system," in Journal of Microencapsulation, 17 (3), 343-362 (2000)], it has been mentioned, "concentration of PLGA used was found to be critical and specifically PLGA/triacetin in range of 0.05-0.22 is covered. It has been explicitly mentioned in the reference that higher PLGA/triacetin concentration produced a sticky, coagulated PLGA mass (a non-microglobule product) and low PLGA/triacetin ratio resulted in poor entrapment and rapid leakage of the microglobule contents". Based on above citation, it is clear that Jain et al. used a specific concentration range of polymer and that too only PLGA with respect to triacetin only, and it does not demonstrate the effect with respect to other polymers and solvent systems mentioned in invention of the instant application. Additionally, it motivates a person ordinary skill in the art not to use higher or lower concentrations, instead to use specific range mentioned in Jain. Whereas, applicants of the present invention have mentioned a range of polymer concentration from 1-90% w/w, preferably from 5-70% w/w and more preferably from 10-60% w/w [paragraph 55] with respect to different polymers and solvents. It is not within the purview of ordinary skill in the art to use wide range of concentration of polymer and too with different polymer systems and solvent systems (as used in present invention) based on teachings of Jain. In other words, prior art (Jain et al) "teaches away" from the claimed invention rather than motivating a person of ordinary skill in the art to do what the applicant of the instant application has done. Additionally, to make a composition with wide range of polymer concentration is "not obvious to try" as there is no teaching, suggestion or motivation behind that to try this along with reasonable expectation of success as Jain et al. itself suggests that success cannot be obtained if concentration of PLGA used is beyond the range specified in Jain. Hence, claimed invention is neither obvious nor expected from Jain et al. Therefore, claim 85 is not obvious over Jain et al.

Hence, as the invention of claims 81 and 85 is not obvious from Jain, it is respectfully respected that this rejection be withdrawn.

The examiner rejected claim 86 under 35 U.S.C. 103 (a) as being unpatentable over Jain ["The manufacturing techniques of various drug loaded biodegradable poly (lactide-co-glycolide) PLGA devices" in Biomaterials, 21, (2000), 2475-2490].

Jain et al. has described the use of only triacetin as a solvent with only PLGA as a polymer and only tween 80 as a emulsifier. Triacetin is a water immiscible solvent whereas the composition of the present invention specifically uses water miscible solvents which can gel in presence of emulsifiers such as sorbitan monopalmitate and sorbitan monostearate in thecontinuous phase. As already described, the composition of Jain et al. is different from the composition of the present invention. Jain et al does not describe the use of other wide range of polymers, solvents or emulsifiers that can be used with such type of composition. Applicants of the present invention provide enough description and examples about the various types of polymers, emulsifiers and solvents that can be used with delivery system of the present invention along with lacunae in the prior art water immiscible solvents used in delivery compositions and also the use of the instant application in overcoming these lacunae. It is not obvious or within purview of person ordinary skill in the art to use suitable concentration of emulsifier for altogether different composition system and solvent system with wide range of polymers, emulsifiers and solvents. It is also "not obvious to try" composition with water miscible solvents, or to make gelled composition using emulsifiers such assorbitan monostearate or sorbitan monopalmitate which can gel water miscible solvents and oil phase as there is no teaching, suggestion or motivation in the prior art related to use of water miscible solvents, which can gel in presence of such emulsifiers.

Therefore, as the invention of claim 86 is not obvious from Jain, it is respectfully respected that this rejection be withdrawn

The examiner rejected claims 88-90 under 35 U.S.C. 102 (a) as anticipated by or, in the alternative under 35 U.S.C. 103 (a) as obvious over Jain ["The manufacturing techniques of various drug loaded biodegradable poly (lactide-co-glycolide) PLGA devices" in Biomaterials, 21, (2000), 2475-2490]. This is respectfully traversed.

However, to reiterate what was discussed above, the drug delivery composition of the present invention is a gelled dispersion, whereas the composition of Jain et al. is not gelled dispersion. Claim 72 also describes the same "gelled matrix". Claim 88-90 is dependent from claim 87, which in turn is dependent from claim 72. Jain describes use of tween 80 only in discontinuous phase and it is further mentioned in Jain that "absence of tween 80 yielded PLGA microglobules which poorly dispersed on coming in contact with water and hardened into an agglomerated PLGA mass (a non-microsphere product)" [See Jain et. al. "Controlled drug delivery from a novel injectable in situ formed biodegradable PLGA microsphere system," in Journal of Microencapsulation, 17 (3), 343-362 (2000)]. Whereas, in the instant application, tweens are not at all being used as emulsifier in discontinuous phase (see examples). Despite the fact that tweens not are being used in discontinuous phase in instant application, applicants are still getting a microparticle product of characteristic size. It is clear from Jain et al. that if tween 80 is not used in discontinuous phase, then it is not within purview of ordinary skill in the art to get microparticles as Jain strongly suggests use of tweens in discontinuous phase. Based on above citations, it is clear that size of microparticles of Jain reference would not obviously fall within the claimed sizes in claims 88-90, following teachings of Jain, as according to Jain person ordinary skill in the art cannot obtain microparticle product without using tween 80 in discontinuous phase and if person ordinary skill in the art is not able to get microparticles then issue of size does not arise. In fact, in other words, prior art (Jain et al) "teaches away" from the claimed invention rather than motivating a person of ordinary skill in the art to do what applicant of the instant application has done. Additionally, to make a composition without using tweens in discontinuous phase is also "not obvious to try" as there is no teaching, suggestion or motivation behind that to try the same along with reasonable expectation of success as Jain et al. itself suggests that success cannot be obtained without using tweens in discontinuous phase. Hence, the claimed invention is neither obvious from Jain et al nor anticipated by Jain et al.

Therefore, as the invention of claims 88-90 is not obvious from Jain, it is respectfully respected that this rejection be withdrawn.

Applicants respectfully submit that the amended claims and patent application is in condition for allowance and notification to that effect is earnestly requested.

Respectfully submitted,

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